FEB 2 2 2012

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 892.2050.

Submitter:	Materialise Dental NV Technologielaan 15 Leuven Belgium
Establishment Reg. Number:	3006638827
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Date Prepared:	September 12, 2011
Trade/ Proprietary Name:	**SimPlant Navigator Personalized Dental Care System**
Common/Usual Name:	System, Image processing. The product uses images acquired from Computerize Tomography (CT) scanners
Classification Name/ FDA Reviewing Branch:	Radiology branch
Device Classification/ Code:	Class II - 21 CFR §892.2050 LLZ

Predicate Device Manufacturer:	SimPlant® 2011; (K110300) Nobel Biocare Guided Surgery Concept; (K050393)
Purpose of the *SPECIAL* 510(k) notice:	The reason for this Special 510k submission is to request clearance for a modificatio to a device that has been cleared under the 510(k) process referred to herein a SimPlant Navigator Personalized Dental Care System (Image processing system referenced under 21 CFR §892.2050 and are considered Class II devices.
Device Description:	**SimPlant Navigator Personalized Dental Care System** provides a method o importing medical imaging information from radiological imaging systems such as Computer Tomography (CT) or Magnetic Resonance Imaging (MRI) to a computer fil that is usable in conjunction with other diagnostic tools and expert clinical judgmen Visual representations of the imaged anatomical structures (e.g. the jaw) are derive allowing for a three-dimensional assessment of the patient without patient contac Dental implant positions including orientations are planned pre-operatively. Compute visualization of the 3D anatomical jaw models, planned implants, planned tooth setu and numerical measurements assist the surgeon in the creation and approval of a pre surgical plan. SurgiGuide® guides and the BIOMET *3i* Navigator Surgical Kit are use intra-operatively to prepare the osteotomy for placement of BIOMET *3i* implants pre operatively determined in the software.
Indications for Use:	SimPlant Navigator Personalized Dental Care System is intended for use as a softwar interface and image segmentation system for the transfer of imaging information fro a medical scanner such as a CT scanner or a Magnetic Resonance scanner. It is als intended as pre-planning software for dental implant placement and surgical treatment. SurgiGuide® guides and the BIOMET *3i* Navigator Surgical Kit, which are used intra operatively to prepare the osteotomy for placement of BIOMET *3i* implants pre operatively determined in the software.
Technological Characteristics :	The predicate devices, SimPlant® 2011 and Nobel Biocare Guided Surgery Concep have a number of very similar and equivalent design /technological characteristic which are very similar and equivalent with the SimPlant Navigator Personalized Dent Care System (see Substantial Equivalence comparison table in Section 14).
Performance Data:	Software Validation in addition to bench top performance testing was conducted t ensure the compatibility of all system components.
Clinical Data:	N/A

Performance Standards:	a. DICOM NEMA PS3.1-3.18: Digital imaging and communication in medicine: 2009 b. ISO14971: Applications of risk management to medical devices: 2007 c. ISO13485: Medical Devices Quality Management System: 2003 d. ISO9001: Quality Management System: 2008 e. ISO10993: Biological evaluations of medical devices: 1992
Substantial Equivalence:	Materialise Dental NV's **SimPlant Navigator Personalized Dental Care Syste** included in this submission have the same intended use, fundamental scientifi technology, similar indications, and principles of operation as the previously cleare SimPlant® 2011; (K110300). Refer to the following substantial equivalence data table:

	Device comparison table		
	Device for premarket notification	K110300	K050393
Trade name	**SimPlant® Navigator Personalized Dental Care System**	**SimPlant® 2011**	**Nobel Biocare The Guided Surgery Concept**
Common name		**SimPlant® Software**	
Classification	Product Code: LLZ 21 CFR. § 892.2050 Classification Panel: Radiology Device Class: II	Product code: LLZ 21 CFR. § 892.2050 Classification Panel: Radiology Device Class: II	Product code: DZE 21 CFR. § 872.3640 Classification Panel: Dental Device Class: II

	Intended Use	The **SimPlant Navigator Navigator Personalized Dental Care System** is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner or a Magnetic Resonance scanner. It is also intended as pre-planning software for dental implant placement and surgical treatment. **The SimPlant Navigator Personalized Dental Care System** can be used with the following Biomet 3I instrument kits and their respective components: implant mounts, cortical perforator, tissue punches, drill positioning handles, twist drills, countersink drills, shaping drills, bone taps, bone profilers, drivers, and ratchets. **SurgiGuide® guides** are intended for single use only.	Materialise Dental's **SimPlant® 2011 software** is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner or a Magnetic Resonance scanner. It is also intended as pre-planning software for dental implant placement and surgical treatment.	The **Guided Surgery Concept** and Teeth-in-an-Hour are indicated for the treatment of single, partially and totally edentulous jaws for placement of implant fixtures with immediate function to restore patient esthetics and chewing function. The following prerequisites must be fulfilled: - Adequate amount of jaw bone - The quality of jaw bone must be judged as adequate
	Material	Software – magnetic media Hardware – • polyamide guides – biocompatible material • stainless steel tubes/sleeves – medical grade	Software – Magnetic media	Software – Magnetic media Hardware • Polyamide guides – biocompatible material

	Design	Software for use in pre-operative planning. The **SimPlant Navigator Personalized Dental Care System** includes **SimPlant® software**, which provides a means for the clinician for image segmentation and advanced pre-operative planning. This enables the clinician to view three-dimensional CT-scan data as well as to plan the case in a virtual three-dimensional environment. The case planning can be used to produce a Surgical Template, thus transferring the virtual case planning into physical tools enabling the surgical installation according to the virtual case planning. The **SimPlant Navigator Personalized Dental Care System** is based upon knowledge of the location and orientation of the implant(s) prior to the surgery. This knowledge enables the production of a SurgiGuide. Aided by the SurgiGuide, the sites can be prepared and the implants placed in the predetermined locations enabling the immediate attachment of the prefabricated temporary or final prosthesis.	Software for use in pre-operative planning. **SimPlant® software** provides a means for image segmentation and advanced pre-operative planning. Surgical templates may be fabricated based on the output of the pre-operative planning.	Software for use in pre-operative planning. The **Guided Surgery Concept** includes a 3D Planning Software that enables the clinician to view three-dimensional CT-scan data as well as to plan the case in a virtual three-dimensional environment. This case planning can be used to produce a Surgical Template, thus transferring the virtual case planning into physical tools enabling the surgical installation according to the virtual case planning. The **Guided Surgery Concept** is based upon knowledge of the location and orientation of the implant(s) prior to the surgery. This knowledge enables the production of a Surgical Template. Aided by the Surgical Template, the sites can be prepared and the implants placed in the predetermined locations enabling the immediate attachment of the prefabricated temporary or final prosthesis.

	Function	The **SimPlant® software** component is used to incorporate the images from either an MRI or CT scan of the affected joint into the specialized planning software. The **SimPlant® software** is used by a qualified surgeon to plan, inspect, fine-tune and approve the pre-surgical plan. The software is used pre-operatively. **SimPlant® software** contains a library of dental implants, and additional instruments for the placement of implants. A **SurgiGuide® guide** may be designed and fabricated based on the output of the pre-operative planning. **SurgiGuide® guides** are patient specific templates that are intended to transfer the pre-operatively determined positioning of the dental implants to the patient intra-operatively, assisting the surgeon in placing dental implants by guiding and marking drill locations.	**SimPlant® software** is used to incorporate the images from either an MRI or CT scan of the affected joint into the specialized planning software. The **SimPlant® software** is used by a qualified surgeon to plan, inspect, fine-tune and approve the pre-surgical plan. The software is used pre-operatively. **SimPlant® software** contains a library of dental implants, and additional instruments for the placement of implants. A **SurgiGuide® guide** may be designed and fabricated based on the output of the pre-operative planning.	
	Programming language	C++	C++	
	Operating system	Windows	Windows	

	Testing	Hardware testing: • Biocompatibility testing of patient contacting components • Sterilization testing • Sterilization dimensional stability test		
		Software testing: • Unit testing • Integration testing • IR testing • Smoke testing • Formal testing • Acceptance testing • Alpha testing • Beta testing	Software testing: • Unit testing • Integration testing • IR testing • Smoke testing • Formal testing • Acceptance testing • Alpha testing • Beta testing	
Conclusion:	**SimPlant Navigator Personalized Dental Care System** and its predicate device: SimPlant® 2011 (K110300) and the Nobel Biocare Guided Surgery Concep (K050393), have the same intended use, indications for use, similar technologica characteristics, and principles of operation. SurgiGuide® guides and the BIOMET *3i* Navigator® Surgical Kit, which are used intra operatively to prepare the osteotomy for placement of BIOMET *3i* implants pre operatively determined in the software. By modifying the SimPlant® 2011 to include the SurgiGuide® and Navigation Surgica Kit does not raise any new questions of safety or effectiveness. The differences noted above do not present new issues of safety or effectiveness for th SimPlant® Navigator Personalized Dental Care System.			

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Carl Van Lierde
QA/RA Manager
Materialise Dental NV
Technologielaan 15
3001 LEUVEN
BELGIUM

FEB 2 2 2012

Re: K112679
Trade/Device Name: SimPlant® Personalized Dental Care System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ, NOF, NDP, and DZA
Dated: January 10, 2012
Received: February 16, 2012

Dear Mr. Van Lierde:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112679

Device Name: **SimPlant® Personalized Dental Care System**

Indications for Use:

SimPlant Navigator Personalized Dental Care System is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner or a Magnetic Resonance scanner. It is also intended as pre-planning software for dental implant placement and surgical treatment.

SurgiGuide® guides and the BIOMET *3i* Navigator Surgical Kit, which are used intra-operatively to prepare the osteotomy for placement of BIOMET *3i* implants pre-operatively determined in the software.

Prescription Use __X__ **Over-The-Counter Use** _____

(Part 21 CFR 801 Subpart D) **AND/OR** **(Part 21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112679